

Message

From: Odusote, Gloria [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ODUSOTE, GLORIA]
Sent: 6/21/2019 10:15:30 PM
To: Ilaria Mormino [Ilaria.Mormino@reagens-group.com]
CC: Mario Berna [mario.berna@reagens-group.com]
Subject: RE: Rif: RE: RE: RE: Concerning P-18 -0105

Hi Ilaria,

Is it possible to schedule a time to talk? There have been a few policy changes since we last spoke and it would be easier to explain over the phone and talk about options and timelines.

Best,
Gloria

From: Ilaria Mormino <Ilaria.Mormino@reagens-group.com>
Sent: Wednesday, June 5, 2019 4:20 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Mario Berna <mario.berna@reagens-group.com>
Subject: Fw: Rif: RE: RE: RE: Concerning P-18 -0105

Good morning Mrs Odusote,
How are you?

With reference to our application P-18 -0105 (see emails below) could you please give us an update on the application status and progress?

Thank you and kind regards

Dr. **Ilaria Mormino**
(Consulente Trasporto Merci Pericolose - DGSA; Regulatory Affairs Representative)
direct: +39 0516639 257
e-mail: ilaria.mormino@reagens-group.com



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www.reagens-group.com
----- Inoltrato da Ilaria Mormino/REAGENS/IT il 05/06/2019 10:16 -----

Da: Ilaria Mormino/REAGENS/IT
Per: "Odusote, Gloria" <odusote.gloria@epa.gov>
Cc: Stefano Gardi/REAGENS/IT@REAGENS, Mario Berna/REAGENS/IT@REAGENS
Data: 17/07/2018 15:42
Oggetto: Rif: RE: RE: RE: Concerning P-18 -0105

Hello Gloria,
thanks for clarifying this.
It is ok for us, that we request a 15 days suspension.

(Please note that I will be on marriage leave from July 21 until August 3rd, if needed during this time you can contact my colleagues Mr Stefano Gardi and Mr Mario Berna, you can find their addresses in C/C
From August 4 to August 19 our offices will be closed for summer holiday)

Thanks and kind regards

Dr. **Ilaria Mormino**

(Consulente Trasporto Merci Pericolose - DGSA; Regulatory Affairs Representative)

direct: +39 0516639 257

e-mail: ilaria.mormino@reagens-group.com



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Da: "Odusote, Gloria" <odusote.gloria@epa.gov>

Per: Ilaria Mormino <Ilaria.Mormino@reagens-group.com>

Data: 16/07/2018 19:11

Oggetto: RE: RE: RE: Concerning P-18 -0105

Hi Ilaria,

The 90 day review period can only be verbally or electronically extended at the request of the submitter. There is a way for us to suspend your case without your request but it is time consuming and generally not used. What this means, is that even though you are waiting on our process, we can only extend the review period at your request.

You can request a suspension for however long you would like, but the largest verbal or by email suspension you can ask for is 15 days. Any longer should be through CDX.

Since your Day 90 is today, I will go ahead and put in the 15 day suspension at your request assuming that you want to continue the review period.

Best,
Gloria

From: Ilaria Mormino [<mailto:Ilaria.Mormino@reagens-group.com>]

Sent: Monday, July 16, 2018 3:58 AM

To: Odusote, Gloria <odusote.gloria@epa.gov>

Subject: Rif: RE: RE: Concerning P-18 -0105

Dear Gloria,

thank you very much for telling me.

Since I am not very familiar with your procedures, it is not very clear to me, why shall we ourselves request a suspension, if our case is waiting for the Office Director.

Is this because our case has an expiry date, which will be postponed if we request a suspension?

Thank you for clarifying this

Best,
Ilaria

Da: "Odusote, Gloria" <odusote.gloria@epa.gov>
Per: Ilaria Mormino <Ilaria.Mormino@reagens-group.com>
Data: 13/07/2018 22:59
Oggetto: RE: RE: Concerning P-18 -0105

Hi Ilaria,

Just wanted to know that your case is still awaiting the decision from the Office Director. Would you like to request a suspension. I would recommend at least a 30 day suspension since there are quite a few cases waiting for his review.

Best,
Gloria

From: Ilaria Mormino [<mailto:Ilaria.Mormino@reagens-group.com>]
Sent: Wednesday, June 27, 2018 6:22 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Mario Berna <mario.berna@reagens-group.com>; Stefano Gardi <stefano.gardi@reagens-group.com>
Subject: Rif: RE: Concerning P-18 -0105

Hi Gloria,
thank you very much for this clarification. Anyway it is ok for us to go for a non-order SNUR.
Best,

Dr. Ilaria Mormino

(Consulente Trasporto Merci Pericolose - DGSA; Regulatory Affairs Representative)

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Da: "Odusote, Gloria" <odusote.gloria@epa.gov>
Per: Ilaria Mormino <Ilaria.Mormino@reagens-group.com>
Cc: Mario Berna <mario.berna@reagens-group.com>, Stefano Gardi <stefano.gardi@reagens-group.com>

Data: 25/06/2018 16:52
Oggetto: RE: Concerning P-18 -0105

Hi Ilaria,

I also realized that there is another clarification I should make. The Consent Order is a legal agreement between the Company that does, soon after the consent order is signed, lead to an official rule making. Your chemical would still be on the inventory if you did a consent order.

Best,
Gloria

From: Odusote, Gloria
Sent: Monday, June 18, 2018 10:59 AM
To: 'Ilaria Mormino' <Ilaria.Mormino@reagens-group.com>
Cc: Mario Berna <mario.berna@reagens-group.com>; Stefano Gardi <stefano.gardi@reagens-group.com>
Subject: RE: RE: RE: RE: RE: RE: RE: Concerning P-18 -0105

Hi Ilaria,

Thanks for your quick response. I will start doing the paperwork. And to clarify, it's not really 2 options. Our current policy is to do a non-order SNUR but some companies that need to commercialize immediately have requested a Consent Order.

Best,
Gloria

From: Ilaria Mormino [<mailto:Ilaria.Mormino@reagens-group.com>]
Sent: Monday, June 18, 2018 10:55 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Mario Berna <mario.berna@reagens-group.com>; Stefano Gardi <stefano.gardi@reagens-group.com>
Subject: Rif: RE: RE: RE: RE: RE: RE: Concerning P-18 -0105

Dear Gloria,

summarizing our conversation, we have two options:

-NON ORDER-SNUR will take 3 or 4 months, at the end it will be officially stated by EPA that the substance does not present any unreasonable risk

or

-CONSENT ORDER will be faster but doesn't lead to an official rulemaking by EPA, just an agreement between EPA and us that the substance may be used.

If we got it correctly, in both cases there are no extra costs nor any need of further data from us, right?

If you confirm so, I talked with my colleague and it is ok for us to go for NON ORDER-SNUR- it is ok to wait for 3/4 months before starting commercializing our product.

Thank you very much and best regards

Dr. Ilaria Mormino

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e-mail: ilaria.mormino@reagens-group.com



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Da: "Odusote, Gloria" <odusote.gloria@epa.gov>

Per: Ilaria Mormino <Ilaria.Mormino@reagens-group.com>

Cc: Mario Berna <mario.berna@reagens-group.com>, Stefano Gardi <stefano.gardi@reagens-group.com>

Data: 18/06/2018 15:56

Oggetto: RE: RE: RE: RE: RE: RE: Concerning P-18 -0105

Hi Ilaria,

I am free now if that works. If not, Wednesday around this time will also work. Yes, that is my number.

Best,

Gloria

From: Ilaria Mormino [<mailto:Ilaria.Mormino@reagens-group.com>]

Sent: Monday, June 18, 2018 6:25 AM

To: Odusote, Gloria <odusote.gloria@epa.gov>

Cc: Mario Berna <mario.berna@reagens-group.com>; Stefano Gardi <stefano.gardi@reagens-group.com>

Subject: Rif: RE: RE: RE: RE: RE: Concerning P-18 -0105

Dear Gloria,

thank you very much, we will be very glad to call you.

Could be today, from 8 to 10 AM (timezone UTC-5)?

Or, if not today, could be on Wednesday, Thursday or Friday morning. Please let me know what time and day is most suitable for you.

Your phone number 001-202 564-1845, right?

Thanks and regards

Dr. Ilaria Mormino

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Da: "Odusote, Gloria" <odusote.gloria@epa.gov>

Per: Ilaria Mormino <Ilaria.Mormino@reagens-group.com>

Cc: Mario Berna <mario.berna@reagens-group.com>, Stefano Gardi <stefano.gardi@reagens-group.com>

Data: 14/06/2018 23:12

Oggetto: RE: RE: RE: RE: RE: Concerning P-18 -0105

Also,

Just so you know. I had a meeting with the eco assessor and the Fate scientists and we came to the conclusion that the water trigger will not be necessary. So you will just be held to the water trigger.

I would definitely recommend you calling me sometime in the next week, so I can explain your regulatory options better.

Best regards,
Gloria

From: Ilaria Mormino [<mailto:Ilaria.Mormino@reagens-group.com>]

Sent: Thursday, June 7, 2018 9:54 AM

To: Odusote, Gloria <odusote.gloria@epa.gov>

Cc: Mario Berna <mario.berna@reagens-group.com>; Stefano Gardi <stefano.gardi@reagens-group.com>

Subject: Rif: RE: RE: RE: RE: Concerning P-18 -0105

Good morning Gloria,
ok, thank you, you can go forward with preparing the documentation.
Please let me know if you need any more info.
Best regards and have a good day

Dr. Ilaria Mormino

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Da: "Odusote, Gloria" <odusote.gloria@epa.gov>

Per: Ilaria Mormino <Ilaria.Mormino@reagens-group.com>

Cc: Mario Berna <mario.berna@reagens-group.com>, Stefano Gardi <stefano.gardi@reagens-group.com>

Data: 07/06/2018 15:43

Oggetto: RE: RE: RE: RE: Concerning P-18 -0105

Hi Ilaria,
Exactly.

Best,
Gloria

From: Ilaria Mormino [<mailto:Ilaria.Mormino@reagens-group.com>]

Sent: Thursday, June 7, 2018 6:53 AM

To: Odusote, Gloria <odusote.gloria@epa.gov>

Cc: Mario Berna <mario.berna@reagens-group.com>; Stefano Gardi <stefano.gardi@reagens-group.com>

Subject: Rif: RE: RE: RE: RE: Concerning P-18 -0105

Dear Mrs Odusote,
thank you for clarifying this.

So, if I understand correctly, once you regulate with non-order SNUR, the substance can be used in US and is TSCA-compliant, provided that these prescriptions (water trigger 50 ppb, gloves and a respirator of APF 50) are observed.

Is it so?

Thanks again and kind regards

Dr. Ilaria Mormino

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Da: "Odusote, Gloria" <odusote.gloria@epa.gov>

Per: Ilaria Mormino <Ilaria.Mormino@reagens-group.com>

Cc: Stefano Gardi <stefano.gardi@reagens-group.com>, Mario Berna <mario.berna@reagens-group.com>

Data: 05/06/2018 16:04

Oggetto: RE: RE: RE: Concerning P-18 -0105

Hi Ilaria,

-A water trigger is a limit. You can find the provision in CRF 721.90 (b)(4) where N=50

"Into the waters of the United States if the quotient from the following formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = N \text{ parts per billion}$$

exceeds the level specified in subpart E of this part when calculated using the methods described in § 721.91. "

-The 2017 Version 6 of the ECHA document (ECHA, 2017) page 315 states "*For substances that sensitise via the respiratory tract, there is still uncertainty regarding the exact mechanisms leading to respiratory sensitisation.*

Based on the current knowledge the induction of respiratory sensitisation can occur via inhalation or dermal exposure to the sensitising substance (Redlich, 2010; Kimber et al., 2015)." The PMN is noted to be a sensitizer. As noted in ECHA (2017), a skin sensitizer has the potential to also induce respiratory sensitization. Both skin and respiratory sensitization are allergic responses to an immune challenge. Thus we are regulating this chemical as a potential respiratory sensitizer in the absence of data.

Best regards,
Gloria Odusote

Gloria Odusote
Chemical Control Division
EPA East
1200 Pennsylvania Ave. NW
Room 4133G, Mail Code 7405M
Washington, DC 20460
202 564-1845
Fax 202 564 9490

From: Ilaria Mormino [<mailto:Ilaria.Mormino@reagens-group.com>]
Sent: Friday, June 1, 2018 9:31 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Stefano Gardi <stefano.gardi@reagens-group.com>; Mario Berna <mario.berna@reagens-group.com>
Subject: Rif: RE: RE: Concerning P-18 -0105

Dear Mrs Odusote,

-what do you mean by water trigger? Is it a limit , or is it a threshold value that triggers some obligations if it is exceeded? And, is it referred to wastewater or anything else?

-Regarding sensitization, the substance is classified as sensitizer as you pointed out- it is a skin sensitizer so it requires gloves as you suggested, but it is not classified as a respiratory sensitizer so perhaps the respirator is not necessary?

The GHS classification has two different risk phrases for sensitization: H317 for skin sensitization and H334 for respiratory sensitization, and this substance has H317 but not H334. Or do you have other evidence regarding respiratory hazard?

Please let me have your point of view (better by e-mail so I can share with my colleagues before reverting to you)

Thanks and have a nice day
Regards

Dr. Ilaria Mormino
(Consulente Trasporto Merci Pericolose - DGSA; Regulatory Affairs Representative)
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Da: "Odusote, Gloria" <odusote.gloria@epa.gov>
Per: Ilaria Mormino <Ilaria.Mormino@reagens-group.com>
Data: 01/06/2018 00:04
Oggetto: RE: RE: Concerning P-18 -0105

Hi Ilaria,

Sorry for the long wait. There are no longer any risk to surface water but we still have concerns that would be addressed with a **water trigger of 50 ppb**. We also have concerns for sensitization, which would require **gloves** and a **respirator of APF 50**.

We generally regulate using non-order SNURs so please let me know if you would like me to go forward with preparing the documentation.

Is there any way we can talk on Monday?

Best,
Gloria

From: Ilaria Mormino [<mailto:Ilaria.Mormino@reagens-group.com>]
Sent: Wednesday, March 28, 2018 2:11 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: Rif: RE: Concerning P-18 -0105

Thank you Gloria.
Have a nice day

Dr. Ilaria Mormino
(Consulente Trasporto Merci Pericolose - DGSA; Regulatory Affairs Representative)

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e-mail: ilaria.mormino@reagens-group.com



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Da: "Odusote, Gloria" <odusote.gloria@epa.gov>
Per: Iaria Mormino <Ilaria.Mormino@reagens-group.com>
Data: 28/03/2018 00:29
Oggetto: RE: Concerning P-18 -0105

Hi Iaria,
I sent your concerns to the eco assessor. I will let you know when I hear a response.
Best,
Gloria

From: Iaria Mormino [<mailto:Ilaria.Mormino@reagens-group.com>]
Sent: Tuesday, March 27, 2018 5:41 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Regulatory <regulatory@reagens-group.com>
Subject: Fw: Concerning P-18 -0105

Dear Mrs Odusote,
we further analysed the impact of our substance on eutrophication issues, and expect it to be negligible based on the following considerations:
Our substance is to be used as ingredient of PVC stabilizers, therefore it will be included in solid matrices, and it is not foreseen to be released in water -as it happens massively with phosphorous-based detergents.
Furthermore, this substance has a very low solubility in water (with estimated solubilities ranging from 5.343×10^{-13} mg/L) therefore the bioavailability for algae is expected to be negligible.
Moreover, eutrophication is due to phosphates and not to phosphites, and it is not likely that it is

converted to phosphate due to its low solubility.

The substance is similar to the linear tri-tridecylphosphite which is listed in the TSCA and has been used safely in the US since many years, the only difference being that the alkyl chain is branched instead of linear.

If you have any more questions for us, please let us know, we will be glad to answer.

Kind regards

Dr. Ilaria Mormino

(Consulente Trasporto Merci Pericolose - DGSA; Regulatory Affairs Representative)

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e-mail: ilaria.mormino@reagens-group.com



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Dear Mrs Odusote,

thank you for your e-mail and for raising this issue about eutrophication. We would like to further investigate this topic, so that we can provide you more detailed information.

If it is ok for you, we would contact you in the next days once we have more information.

Thanks and looking forward to talk to you.

Kind regards

Dr. Ilaria Mormino

(Consulente Trasporto Merci Pericolose - DGSA; Regulatory Affairs Representative)

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e-mail: ilaria.mormino@reagens-group.com



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----- Inoltrato da Ilaria Mormino/REAGENS/IT il 12/03/2018 09:03 -----

Da: "Odusote, Gloria" <odusote.gloria@epa.gov>

Per: "regulatory@reagens-group.com" <regulatory@reagens-group.com>

Data: 09/03/2018 03:57

Oggetto: Concerning P-18 -0105

Hi Robert,

My name is Gloria Odusote and I am the program manager for you case. We identified some health concerns due to sensitization and irritation, which can be addressed with PPE. However, there were some eco risks identified, which we will need more information to address. We had concerns for eutrophication in water systems based on the presence phosphates. I will not be in tomorrow but I would like to talk to you on Monday, if that is possible.

Best regards,
Gloria Odusote

Gloria Odusote
Chemical Control Division
EPA East
1200 Pennsylvania Ave. NW
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Washington, DC 20460
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Fax 202 564 9490